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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. KUN WO FOOD PRODUCTS, INC., a corporation, and ZI XING LIU and ZI CHEN LIU, individuals, Defendants.	Civil No. _16-1927_____ [~~PROPOSED~~] CONSENT DECREE OF PERMANENT INJUNCTION

[~~PROPOSED~~] CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a Complaint for Injunction against Kun Wo Food Products, Inc., a corporation, and Zi Xing Liu and Zi Chen Liu, individuals (collectively, "Defendants"), and Defendants, without admitting or denying the

allegations of the Complaint, having appeared and consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and all parties to this action.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act").

3. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated under 21 U.S.C. § 342(a)(4), in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

4. Defendants represent to the Court that, as of the end of the business day on April 11, 2016, they are not engaged in receiving, preparing, processing, packing, holding, or distributing any type of food at or from any location.

5. If Defendants intend to resume receiving, preparing, processing, packing, holding, or distributing food at or from any facility at any time in the future, they must first notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations and comply with paragraphs 6(a) – (i) of this Decree. This notice shall identify the type(s) of food Defendants intend to receive, prepare, process, pack, hold, or distribute at or from any facility. Defendants shall not resume operations until FDA has inspected the facility(ies) and operations pursuant to paragraph 6(g), Defendants have paid the costs of such inspections as required by paragraph 6(h), and Defendants have received written

notice from the FDA, as required by paragraph 6(i), and shall resume operations only to the extent authorized in FDA's written notice.

6. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, and "doing business as" entities) (collectively, "Associated Persons"), who receive notice of this Decree by personal service or otherwise, are restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court from directly or indirectly receiving, preparing, processing, packing, holding, and/or distributing any article of food at or from 2939 16th Street, San Francisco, California 94103, or any other location(s) at which Defendants now or in the future directly or indirectly receive, prepare, process, pack, hold, and/or distribute articles of food, ("Defendants' Facility" or "the Facility") unless and until:

a. Defendants retain, at their expense, an independent expert (the "Expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified (1) to develop and ensure the adequate implementation of a Pathogen Control Program, (2) to establish methods, facilities, and controls at Defendants' Facility to ensure that food is prepared, processed, packed, held, and distributed in compliance with current good manufacturing practice ("cGMP") regulations for food (set forth at 21 C.F.R. Part 110), and (3) to inspect the Facility and determine whether Defendants' methods, facilities, and controls are operated and administered in conformity with the Act, cGMP regulations at 21 C.F.R. Part 110, and this Decree. Within two (2) calendar days of retaining the Expert, Defendants shall notify FDA in writing of the name and qualifications of the Expert;

b. Defendants retain, at their expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, which is qualified to analyze environmental and food samples collected at Defendants' Facility for the presence of *Listeria monocytogenes* ("*L. mono*") in a manner that is acceptable to FDA. Within two (2) calendar days of retaining the Laboratory, Defendants shall provide FDA with a copy of the service contract, which shall contain provisions acceptable to FDA for conducting environmental and food analyses;

c. Defendants' Expert, in consultation with the Laboratory and after reviewing all of the FDA inspectional observations to date, develops a written Pathogen Control Program to FDA's satisfaction. The Pathogen Control Program shall include, at a minimum:

(i) A written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, processing, packing, holding, and distributing articles of food to minimize the risk of introducing *L. mono*, *B. cereus*, *Salmonella*, *E. coli*, *S. aureus*, and other pathogenic organisms, chemicals, and filth into the food, and to ensure that the food is not adulterated within the meaning of 21 U.S.C. § 342(a). Such methods, facilities, and controls shall include, but not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' Facility and all equipment therein suitable for use in receiving, preparing, processing, packing, holding, and distributing articles of food, and instituting standard sanitation operating procedures ("SSOPs") to ensure that the Facility and equipment therein are continuously maintained in a sanitary condition;

(ii) Written procedures for production and process controls designed to minimize the potential for the growth of pathogens, including but not limited to, *L. mono*, *B. cereus*, *Salmonella*, *E. coli*, and *S. aureus*, and to protect food against contamination. Such

procedures shall include, but not be limited to, production and process controls to ensure that Defendants: (a) take all reasonable precautions throughout food manufacturing operations to ensure that production procedures do not contribute contamination from any source; (b) conduct food manufacturing under conditions and controls that minimize the potential for bacterial growth and for the contamination of food; (b) hold food that can support the rapid growth of pathogens in a manner that prevents the food from becoming adulterated within the meaning of the Act; (c) handle work-in-process in a manner that protects it against contamination; (d) use and maintain equipment, containers, and utensils used to convey, hold, or store food in a manner that protects food against contamination; and (e) perform mechanical manufacturing steps in a manner that protects food against contamination;

(iii) A written employee training program (in English, Cantonese, and any other language that is necessary to convey the substance of the training program to the employees) that includes, at a minimum, instructions on sanitary food handling techniques and documentation that each employee has received such training. The employee training program shall include, at a minimum, basic training for all employees on the importance of controls for bacterial pathogens including but not limited to *L. mono*, *B. cereus*, *Salmonella*, *E. coli*, and *S. aureus*, and their role in control strategies for bacterial pathogens, training for all employees who handle food or work in areas where finished product is exposed to the environment to ensure that they understand how to prevent cross-contamination of food, and training for all employees who conduct cleaning and sanitation tasks to ensure that they understand the sanitation procedures necessary to minimize the risk of bacterial pathogens including but not limited to *L. mono*, *B. cereus*, *Salmonella*, *E. coli*, and *S. aureus*, in the Facility. Defendants' Expert shall ensure that each employee fully understands the substance of the employee training program;

(iv) A written program for environmental monitoring and testing of Defendants' Facility to ensure that organisms including, but not limited to *Listeria species* ("*L. spp.*") are systematically controlled and that the pathogen *L. mono* does not occur in finished products. Environmental monitoring shall include, but not be limited to, collecting swab samples from food-contact surfaces, equipment, and other environmental sites throughout the Facility (where the raw ingredients, in-process, and finished articles of foods are received, prepared, processed, packed, held, and/or distributed, and common areas that could be reservoirs for cross-contamination), and analyzing the environmental samples for the presence of *L. mono* and other *L. spp*. Sampling shall be conducted according to a method that specifies, at a minimum: how, where, and when to sample; and, the number and frequency of samples to be collected. Defendants shall ensure that the results of all analyses conducted pursuant to this paragraph are sent to FDA within two (2) calendar days after receipt by Defendants;

(v) A written plan for effective remedial action, including, but not limited to intensified sanitation and intensified sampling measures, that Defendants shall implement if *L. spp*., *L. mono*, or any other pathogenic organism is detected during the sampling and testing conducted pursuant to paragraph 6(c)(iv); and

(vi) A sampling and testing plan appropriate for conducting finished product testing in accordance with paragraph 8(b) below; and

d. FDA approves, in writing, the Pathogen Control Program developed by the Expert;

e. Defendants complete the following requirements:

(i) Defendants assign continuing responsibility for implementing and monitoring the FDA-approved Pathogen Control Program to a person who, by reason of

background, education, training, or experience, is qualified to maintain Defendants' Facility in a sanitary condition and implement all necessary remedial action, and Defendants provide such person with the authority to achieve all necessary remedial action;

(ii) Defendants make the FDA-approved Pathogen Control Program available and accessible (in English, Cantonese, and any other language necessary to convey the substance of the document) to their officers, employees, and all other people who perform duties at Defendants' Facility;

(iii) Defendants successfully complete the FDA-approved employee training program;

(iv) Defendants, at their expense, clean and sanitize the Facility and equipment therein and make improvements to render the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food in accordance with this Decree, the Act, and 21 C.F.R. Part 110, and Defendants ensure that the Facility and equipment therein will be continuously maintained in a sanitary condition;

(v) Defendants report to FDA in writing the actions they have taken to bring their operations into compliance with this Decree, the Act, and 21 C.F.R. Part 110, including:

(A) Documentation that they have cleaned and sanitized the Facility and equipment therein and made improvements, thereby rendering the Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing articles of food, and documentation that they have conducted environmental monitoring and testing in accordance with the FDA-approved Pathogen Control Program; and

(B) Specific measures that they have taken to address each of the cGMP deficiencies observed by FDA during all prior FDA inspections; and

(C) Defendants destroy, under FDA's supervision, and in accordance with the procedures provided in paragraph 7, all articles of food in Defendants' custody, control, or possession as of the date of entry of this Decree;

f. The Expert conducts a comprehensive inspection of Defendants' Facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute articles of food to determine whether Defendants have effectively implemented all corrective actions and are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The Expert shall verify, with supporting documentation, that (1) Defendants have corrected all of the cGMP deficiencies observed by FDA during all prior FDA inspections, specifying each FDA inspectional observation and Defendants' corrections thereof, and (2) Defendants' Facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute articles of food are, in the Expert's opinion, in compliance with this Decree, the Act, and 21 C.F.R. Part 110. The Expert shall submit a written report of all findings, with supporting documentation, to Defendants and FDA concurrently, within ten (10) calendar days after completion of the inspection;

g. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and 21 C.F.R. Part 110, inspects Defendants' Facility, including the buildings, sanitation-related systems, equipment, utensils, labeling, and all articles of food and relevant records contained therein;

h. Defendants pay all costs of inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews for FDA's oversight with respect to paragraph 6, at the rates set forth in paragraph 15; and

i. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 6(a)—(f) and (h) of this Decree, the Act, and 21 C.F.R. Part 110. In no circumstance shall FDA's silence be construed as a substitution for written notification.

7. Within fifteen (15) calendar days after entry of this Decree, Defendants shall, under FDA's supervision and pursuant to a written destruction plan approved in writing by FDA prior to implementation, destroy all articles of food in Defendants' custody, control, or possession as of the date of entry of this Decree. Defendants shall bear the costs of destruction and the costs of FDA's supervision incurred under this paragraph. Defendants shall not dispose of any article of food in a manner contrary to the provisions of the Act, any other federal law, or the laws of any State or Territory, as defined in the Act, in which the articles of food are disposed.

8. Upon resuming operations after complying with paragraph 6, and receiving FDA's written notification pursuant to paragraph 6(i), Defendants shall meet the following requirements:

a. Defendants shall continuously implement the Pathogen Control Program approved by FDA pursuant to paragraph 6(d). In the event that the Expert or the Auditor (described in paragraph 8(c) below) determine that the Pathogen Control Program needs to be revised, Defendants shall provide proposed changes to FDA in writing at least twenty (20)

calendar days prior to the planned implementation, and shall not implement their proposed changes unless and until FDA approves those changes in writing;

b. Defendants shall conduct finished product testing, in accordance with the finish product sampling and testing plan in the FDA-approved Pathogen Control Program, in the following manner:

(i) Defendants shall test for *L. mono* in representative samples from each lot of rice noodles per day for at least thirty (30) consecutive production days;

(ii) After completing the testing provided for in paragraph 8(b)(i), Defendants shall test at least one lot of rice noodles per every seven (7) production days for the next three (3) months;

(iii) After completing the testing under paragraph 8(b)(ii), Defendants shall test at least one lot of rice noodles per month for the next twelve (12) months; and

(iv) After completing the testing under paragraph 8(b)(iii), Defendants shall test at least one lot of rice noodles every three (3) months thereafter.

Defendants shall ensure that the results of all testing conducted pursuant to paragraph 8(b) are forwarded to FDA within two (2) calendar day after receipt by Defendants. If any laboratory test completed pursuant to paragraphs 8(b) detects the presence of *L. mono* or any other pathogen in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall destroy, at Defendants' expense, under FDA's supervision, and according to a written destruction plan approved in writing by FDA prior to implementation, all articles of food prepared, processed, packed, and/or held from the time the laboratory sample(s) testing positive for *L. mono* or any other pathogen were collected. Defendants may resume production only when they have determined and corrected the cause of

the contamination, and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and 21 C.F.R. Part 110. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under this paragraph anew.

c. Defendants shall retain an independent person (the "Auditor") who shall meet the criteria for, and may be the same person as, the Expert, to conduct audit inspections of Defendants' Facility and the methods, processes, and controls used to receive, prepare, process, pack, hold, label, and distribute articles of food, as follows:

(i) Within thirty (30) calendar days after Defendants resume their operations after completing the requirements of paragraph 6, the Auditor shall conduct a comprehensive audit inspection of Defendants' Facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute articles of food to determine whether Defendants are operating in compliance with this Decree, the Act, and 21 C.F.R. Part 110, and to identify any deviations from those requirements. The Auditor shall submit an Audit Report documenting all findings to Defendants and FDA concurrently, within ten (10) calendar days after completing the audit inspection; and

(ii) Thereafter, the Auditor shall conduct one audit inspection every three (3) months for one year, and then one audit inspection every six (6) months for the next two (2) years. Beginning in the fourth year after Defendants resume their operations after completing the requirements of paragraph 6, the Auditor shall conduct audit inspections annually unless FDA informs Defendants in writing that more frequent audit inspections and reporting are required. During each audit inspection, the Auditor shall verify that Defendants' Facility and the methods and controls that Defendants use to receive, prepare, process, pack, label, hold, and

distribute articles of food are in compliance with the requirements of this Decree, the Act, and 21 C.F.R. Part 110, and shall certify compliance in the Audit Report. As a part of every Audit Report (except the first one), the Auditor shall assess the adequacy of actions taken by Defendants to correct all previous audit observations indicating that Defendants are not in compliance with this Decree, the Act, or 21 C.F.R. Part 110. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or 21 C.F.R. Part 110, Defendants shall make all necessary corrections within ten (10) calendar days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary.

9. If, after notifying FDA of the name of the Laboratory retained to conduct sample analyses pursuant to paragraph 6(b), Defendants terminate or in any way alter their service contract with the Laboratory, Defendants shall notify FDA within seven (7) calendar days after terminating or altering the service contract. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new laboratory to FDA within seven (7) calendar days after retaining the new laboratory.

10. Upon entry of this Decree, and after receiving FDA's written notification pursuant to paragraph 6(i), Defendants and their Associated Persons are restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any of the following acts:

a. Violating 21 U.S.C. § 331(k), by causing articles of food that are held for sale after shipment of one or more components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and

b. Failing to implement and continuously maintain the requirements of this Decree.

11. If, at any time after entry of this Decree, FDA determines, based on an inspection, a report or data prepared or submitted by Defendants, the Expert, or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, Defendants have violated the Act or its implementing regulations, or additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and direct Defendants to take appropriate corrective action, including, but not limited to, directing Defendants to immediately take one or more of the following actions:

a. Cease receiving, preparing, processing, packing, labeling, holding, and/or distributing any and all articles of food;

b. Recall, at Defendants' expense, all articles of food that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

c. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Decree;

d. Submit additional reports or information to FDA as requested;

e. Submit samples to a qualified laboratory for analysis;

f. Institute or implement any of the requirements set forth in this Decree;

g. Issue a safety alert; and/or

h. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

This remedy shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in paragraph 11, at the rates specified in paragraph 15.

12. The following process and procedures shall apply in the event that FDA issues an order under paragraph 11:

a. Unless a different time frame is specified by FDA in its order, within ten (10) business days after receiving such order, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may also propose specific alternative actions and timeframes for achieving FDA's objectives.

b. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification, and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

c. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and may, if they so choose,

bring the matter before this Court on an expedited basis. While seeking Court review, Defendants shall continue to diligently implement and comply with FDA's order, unless and until the Court stays, reverses, or modifies FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 23.

d. The process and procedures set forth in paragraphs 12 (a)–(c) shall not apply to any order issued pursuant to paragraph 11 if such order states that, in FDA's judgment, the matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such order, immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief while they implement FDA's order. Any judicial review of FDA's order under this paragraph shall be made pursuant to paragraph 23.

e. Any cessation of operations or other action described in paragraph 11 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendants may resume operations. After a cessation of operations, and while determining whether Defendants appear to be in compliance with the Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

13. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' operations and take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to Defendants' places of business, including, but not limited to, all buildings, equipment, raw ingredients, in-process materials, finished products, containers,

packaging material, labeling, and other material therein; take photographs and make video recordings; take samples of Defendants' raw ingredients, in-process materials, finished products, containers, packaging material, labeling, and other material; and examine and copy all records relating to the receipt, preparing, processing, packing, labeling, holding, and distribution of any and all of Defendants' products and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

14. Defendants shall immediately provide any information and records to FDA upon request regarding the receipt, preparing, processing, packing, labeling, holding, and distribution of Defendants' products. Defendants shall maintain copies of their Pathogen Control Program, along with copies of all records required by the Pathogen Control Program, 21 C.F.R. Part 110, or this Decree, at the Facility, and any other location(s) at or from which Defendants receive, prepare, process, pack, label, hold, and/or distribute articles of food, in a location where the records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three (3) years after the date the records are prepared.

15. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree at the standard rates prevailing at the time the costs are incurred. Defendants shall make payment in full to FDA within twenty (20) calendar days of receiving written notification from FDA of the costs. As of the date that this Decree is entered by the Court, these rates are: $90.65 per hour or fraction thereof per

representative for inspection and investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses when necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

16. Within seven (7) calendar days after entry of this Decree, Defendants shall prominently post a copy of this Decree (in English, Cantonese, and any other language necessary to convey the substance of the Decree) in a conspicuous location in an employee common area at Defendants' Facility and shall ensure that the Decree remains posted for as long as the Decree remains in effect. Within ten (10) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit, from an individual with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

17. Within fifteen (15) calendar days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree (in English, Cantonese, and any other language necessary to convey the substance of the Decree). Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit, from an individual with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

18. Within fifteen (15) calendar days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (return receipt requested) to

each and all of their Associated Persons. Within twenty (20) calendar days after entry of this Decree, Defendants shall provide FDA with an affidavit, from an individual with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who have received a copy of this Decree, and attaching a copy of the executed certified mail return receipts.

19. In the event that any of the Defendants becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested) to such Associated Person(s). Within seven (7) calendar days of each time that any of the Defendants becomes associated with any additional Associated Person, Defendants shall provide FDA with an affidavit, from an individual with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all Associated Persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

20. Defendants shall notify FDA in writing at least twenty (20) calendar days before any change in ownership, name, or character of their business that occurs after entry of this Decree (including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, lease, sale, or any other change in the structure or identity of Kun Wo Food Products, Inc., or the assignment, lease, or sale of any business assets such as buildings, equipment, or inventory) that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any prospective successor or assign at least thirty (30) calendar days prior to any sale or assignment. Defendants shall provide FDA with an

affidavit of compliance with this paragraph no later than twenty (20) calendar days prior to such assignment or change in ownership.

21. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America: seven thousand dollars ($7,000) in liquidated damages for each day such violation continues; an additional sum of five thousand five hundred dollars ($5,500) in liquidated damages per day per violation, for each violation of this Decree, the Act, or its implementing regulations; and an additional sum in liquidated damages equal to twice the retail value of any product distributed in violation of this Decree, the Act, or its implementing regulations. The liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

23. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any

FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

24. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Injunction Decree Correspondence" and addressed to the District Director, United States Food and Drug Administration, San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, California 94502, and shall reference this civil action by case name and civil action number.

25. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED, this 27th day of April, 2016.

IT IS SO ORDERED
UNITED STATES ~~DISTRICT JUDGE~~ Magistrate Judge
Judge Donna M. Ryu
UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

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Entry consented to:

For Defendants

_/s/ Signature on File_____
ZI XING LIU, Individually and on behalf of
KUN WO FOOD PRODUCTS, INC.

_/s/ Signature on File_____
ZI CHEN LIU
Individually

_/s/ Signature on File_____
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